

REMARKS

Applicants appreciate the indication that all prior rejections have been withdrawn.

Claims 23, 26, 27, 32, 35, 48, 50, 60, 62 and 73 have been amended and claims 74-76 have been added. Claim 37 also has been cancelled without prejudice. No new matter has been added by virtue of the amendments. For instance, amendments have been made merely to correct certain inadvertent spelling-type matters. Support for the amendments also appears e.g. at page 4, lines 3-6 and 14-16 and page 5 of the application.

It is believed the non-substantive objection to claim 26 has been obviated by the amendments made herein.

Claims 23-30, 32, 33-40, 42-44, 47-52, 54, 55, 58-65, 67-69, 72, 73 were rejected under 35 U.S.C §102(e) over Paques et al. (U.S. Patent Application 2003/0171722). In particular, the Office Action states:

Paques et al. discloses a method for treating an eye with a device comprising a piercing member (4) with an outer diameter less than 25 gage [0053] allowing the puncture location to self-seal and having a flexible plastic tube therein [0087] to administer a therapeutic substance to the eye. The device is used to treat conditions such as a vascular occlusion [0039] by advancing the device transconjunctively and piercing the sclera of the eye and delivering a therapeutic agent subretinally.

Applicants respectfully traverse the rejection.

Applicants' claims 23, 27 and 60 (the only pending independent claims) read as follows:

Claim 23. A method for treating an eye comprising:
inserting into an eye a device comprising a piercing member and a cannula insertable within the piercing member, the cannula having a length longer than the length of the piercing member,
wherein the piercing member is inserted into the sclera of the eye and the device is advanced transconjunctivally through the sclera of the eye.

Claim 27. A method of treating an eye, comprising:
piercing the eye with a piercing member and inserting the piercing member into the eye, the piercing member having a proximal end and a distal end and a lumen defined therebetween;
advancing a cannula through the piercing member lumen;
guiding the cannula to a treatment site; and
treating the treatment site.

Claim 60. A method for treating an eye comprising:
inserting into an eye a device comprising an outer member and a cannula within the outer member and within a piercing member, the cannula having a length extending or extendable beyond the outer member distal end, wherein the device is inserted into the eye by piercing the eye with the piercing member and advancing the piercing member into the eye.

The cited Paques document reports a certain injection device where a sclerotomy (surgical incision) is first made in the eye such as with a first instrument, and then a distinct injection device is then inserted into the eye through the sclerotomy. See Paques at paragraph 48.

Paques does not describe or suggest a method wherein a device is inserted into the eye by piercing the eye with the piercing member followed by inserting the piercing member into the eye, as Applicants disclose.

Further, Paques does not describe or suggest a method wherein the piercing member creates an opening in the eye that is self-sealing as recited in Applicants' claims 74-76. Rather, according to Paques, a conventional approach is used wherein an incision is made through which a device enters the eye. See, for instance, Paques at paragraph 48. Such incisions would typically require the use of sutures or other types of sealing techniques following removal of the device from the eye.

In view thereof, reconsideration and withdrawal of the rejection are requested. See, for instance, *In re Marshall*, 198 USPQ at 346 ("[r]ejections under 35 USC 102 are proper only when the claimed subject matter is identically disclosed or described in the prior art.").

Claims 31, 45, 46, 56, 57, 70, 71 were rejected under 35 U.S.C §103(a) over Paques et al. (U.S. Patent Application 2003/0171722) in view of del Cerro et al. (U.S. Patent 5,409,457). In particular, the Office Action states:

Paques et al., as described above, teaches a device for subretinal delivery of a therapeutic agent wherein the device has an outer piercing member and an inner cannula, but fails to teach withdrawal of fluid from the eye.

Del Cerro et al. teaches a device comprising a tip for penetrating the subretinal region of the eye to deliver a therapeutic agent or withdraw fluid from the eye (column 4, line 31).

It would have been obvious to one skilled in the art at the time of invention to withdraw fluid from the eye in order to reduce the pressure in the eye, as well as to deliver therapeutic fluid to treat the disease or injury, both actions possible with the syringe connected to the device of Paques.

Applicants respectfully traverse the rejection.

As discussed above, the Paques document does not describe or otherwise suggest a method for treating an eye wherein a device is inserted into the eye by piercing the eye with a piercing member and the piercing member is inserted into the eye, as Applicants disclose. Rather, Paques reported method entails creation of a first incision through which a device then may be inserted into the eye. Additionally, such incisions as reported by the Paques document are not self-sealing but, rather, require the use of sutures or other sealing techniques to close the incision, in contrast to Applicants' claims 74-76.

Additionally, as Dr. Varner discussed with the Examiner at the prior interview, del Cerro does not advance the reported device transconjunctivally as recited in Applicants' claim 23. See, for instance, Figure 2 of del Cerro et al.

In fact, del Cerro specifically *teaches against* transcleral applications and states the following at column 1, lines 36-41 regarding other approaches (bold emphasis added):

* * * they carry out sample delivery by penetrating an anterior part of the eye, i.e. via a transcorneal or **transcleral route**, which creates the risks of corneal ulceration, cataract formation, and other anterior penetration problems.

The insertion approach reported by del Cerro also is distinct from Paques. See, for instance, Fig. 4 of Paques. Clearly, then, the skilled worker would not have so carefully combined selected aspects of Paques and del Cerro as proposed by the instant rejection.

In view thereof, reconsideration and withdrawal of the rejection are requested.

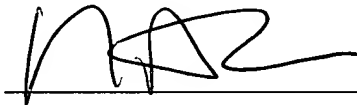
Claims 41, 53 and 66 were rejected under 35 U.S.C §103(a) over Paques (U.S. Patent Application 2003/0171722) in view of Bowman et al. (U.S. Patent 6,378,526). As the rejection is understood, Bowman et al. is cited for administration of a steroid. The rejection is traversed.

The Bowman et al. report of steroid administration clearly does not remedy the noted deficiencies of Paques. As discussed above, Paques does not describe or suggest a method for treating an eye wherein a device is inserted into the eye by piercing the eye with a piercing member followed by inserting the piercing member through and into the eye.

Reconsideration and withdrawal of the rejection are requested.

It is believed the application is in condition for immediate allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Corless', written over a horizontal line.

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